

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 1/17/12 have been fully considered but they are not persuasive.
2. Applicant argues that the system of Savage measures the amount of fluid introduced into a patient, but does not provide for delivering a desired volume of fluid. The Examiner disagrees. Savage discloses that during certain procedures, a considerable amount of fluid must be introduced at flow rates of more than 500 ml per minute (col. 1, lines 45-50). The device of Savage further allows the user to track the amount of fluid introduced. By allowing the user to deliver any amount of fluid and track the volume delivered, the system of Savage allows the user to precisely deliver a desired amount of fluid. Applicant further argues that the device of Savage continuously introduces and simultaneously removes fluid from the patient. This does not appear to be a function that is precluded by the claim language. Regardless, the inflow and outflow systems of Savage are not connected to a single pump mechanism, and therefore while the fluid is delivered and removed simultaneously, these actions are independent of each other and monitored independently so the act of removing fluid from the patient does not affect the system's ability to deliver a desired volume of fluid.
3. Applicant argues that the system of Savage does not disclose a peristaltic pump capable of delivering fluid in the claimed range. The Examiner does not contend that it does. As can clearly be seen in the prior Office Action, Ognier is relied upon to teach a peristaltic pump having the claimed delivery capabilities (see office action, pages 5-6, paragraph 16).

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4. Applicant further argues that Savage teaches against the delivery of a desired volume of fluid. Applicant argues that delivering a desired volume of fluid to a patient may result in unsafe pressures, and the device of Savage is designed to prevent this. The Examiner does not find this argument convincing. First, as stated above, Savage discloses that the device is capable of delivering very high volumes of fluid. Second, Savage discloses that the pump has a safety feature that prevents over pressurization. Over pressurization can occur when the inflow or outflow tubes become clogged which can lead to an unsafe condition. However, when the device is functioning properly, the pump is capable of delivering fluid at high volumes and high rates. The fact that this safety feature is included in the device speak to the fact that delivering a high volume of fluid is desired, because if only a small volume of fluid was intended to be delivered there would be no chance of over pressurization of the body cavity.

5. Applicant argues that Ognier is focused on controlling the flow rate of fluid and is not designed for delivering a desired volume. The Examiner does not find this argument convincing because Ognier is not relied upon for such a teaching. As stated in the prior Office Action, Ognier is relied upon to teach that a peristaltic pump may be used in a device such as the one of Savage. Furthermore, Applicant's argument that the peristaltic pump is not designed for delivering a desired volume of fluid is not convincing. Flow rate is directly proportionate to volume, and so a device that allows the user to control the flow rate also allows the user to control the volume of fluid delivered.

6. Applicant argues that Ognier fails to teach a processor for processing the electric output from a strain gauge sensor. Again, the Examiner points Applicant to the prior Office Action

where *Ognier* is relied upon only to teach a peristaltic pump. The processor is clearly disclosed by Savage and therefore, need not be further taught by a secondary reference.

7. Applicant argues that the first and second supplemental declarations from Dr. Mark Jewell establish that the method and systems available prior to introduction of the claimed invention did not satisfy a long felt need for rapidly and accurately delivering fluids in lipoclastic procedures or for filling breast implants or sizers. The Examiner did not find these declarations convincing as will be described in detail below.

8. The amendments to the claims overcome the rejection under 35 U.S.C. 112, second paragraph in the prior action.

***Response to Amendment***

9. The Declarations under 37 CFR 1.132 filed 1/17/12 is insufficient to overcome the rejection of claims 1-18 based upon Savage in view of Ognier and Dunberger or Maddock as set forth in the last Office action because:

10. Dr. Jewell states the prior to the release of the instant invention, he was not aware of any device that could deliver fluid with the necessary speed and accuracy for use in lipoclastic procedures. The Examiner does not contend that such a device exists. However, as described in the rejection below, such a device would have been obvious to one of ordinary skill in the art. Furthermore, lipoclastic procedures were being performed prior to the introduction of the instant invention and so one must assume that the prior devices had the necessary capabilities for use in such procedures.

11. The first supplemental declaration argues that accurately monitoring the amount of fluid infiltrated into a patient is critical, and power infusers and peristaltic pump systems used prior to

the instant invention relied on line markings on an IV bag and are therefore subject to inaccurate readings. The Examiner does not find this argument convincing because the use of weight measurements, specifically strain gauges, is a well established method of improving the ability of the user to monitor the amount of fluid infiltrated into a patient. As disclosed by Savage, "In order to monitor fluid levels, many irrigant bags are prefilled by the manufacturer or include fluid level markings" (col. 1, lines 25-27). Savage goes on to say that "the irrigant bags routinely do not provide an accurate volume measurement" and therefore, "this method of measuring patient fluid level retention is inaccurate" (col. 1, lines 30-32, 35-36). Savage also recognizes that excessive delivery of fluids may be dangerous and even fatal (col. 1, lines 15-18). Savage recognizes the problems associated with the prior means for monitoring fluid delivery and provides an improved method, namely, measuring the fluid weight delivered using a strain gauge (col. 2, lines 15-16). Therefore, while this is a recognized problem in the art, it has already been solved.

12. The Declaration states that the use of IV systems do not deliver fluid rapidly enough or with sufficient pressure for use in lipoplasty procedures and specifically points to previously cited documents by Wheeldon, Hadzic and Ruiz. These references are not currently being relied upon in the rejection and so they will not be addressed further herein.

13. The Declaration also states that the devices of DeSatnick, Savage, and Ognier describe the use of continuous flow systems that do not deliver a desired volume of fluid. As addressed above, the Examiner does not find this argument convincing. Savage discloses that the device can deliver high volumes of fluids as high flow rates, and that the amount of fluid introduced is

precisely measured. Therefore, the device of Savage is clearly capable of delivering a desired amount of fluid.

14. The second supplemental Declaration contains similar arguments directed to the use of the device for filling implants or sizers. This declaration is not convincing for the reasons stated above. The Examiner does not contend that the claimed device exists, but that it would have been obvious to one of ordinary skill in the art, given the teachings available in the art.

15. The Declarations do not provide evidence to support that the combinations provided in the rejection are not obvious.

#### *Claim Objections*

16. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 21-29 have been renumbered 20-28.

#### *Claim Rejections - 35 USC § 103*

18. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

19. **Claims 1, 4, 6, 9, 19, 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage et al (US 6,319,221) in view of Ognier et al (US 5,178,606).**

20. Savage discloses a system for rapidly delivering and accurately monitoring the delivery of a desired volume of sterile fluid to a targeted anatomical site comprising a strain gauge sensor

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108, a container of sterile fluid 12 connected to the strain gauge sensor so that the sensor will generate an electrical output proportional to the weight of the fluid in the container (col. 3, lines 42-46), a pump 306 for rapidly pumping the desired amount of fluid to the site (col. 10, lines 64-67), a sterile tubing set, a processor 24 for processing the electrical output from the strain gauge to determine the volume of fluid delivered during the procedure (col. 4, lines 43-45), the processor is not electrically connected to the pump (see fig. 9), and a display 64 for displaying the amount of fluid delivered (col. 6, lines 52-55). The device is capable of being used in a lipoplasty procedure or to fill an implant or a sizer because it delivers fluid to a site within the body at a controlled rate.

21. Regarding claims 1, 19, Savage discloses that the device typically operates at flow rates of more than 500 ml/min (col. 1, lines 49-50) and that the device is capable of delivering indefinite amounts of fluid due to the capability of the device to allow empty containers to be replaced with full containers (col. 7, lines 29-33), but fails to disclose a peristaltic pump that is adjustable by a user within the claimed range. Ognier teaches an irrigation and aspiration apparatus for use in an endoscopic surgery procedure comprising a peristaltic pump for delivering sterile fluid to the patient, the pump is adjustable to deliver fluid at rates of 0 to 700 ml/min (col. 3, line 65 - col. 4, line 4). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Savage to include a peristaltic pump as taught by Ognier so that the device can meet the requirements for use in a variety of procedures. A versatile device is desirable because using one pump for multiple types of procedures reduces the number of devices a hospital must purchase.

22. Regarding claims 4, 6, 9, 20 Savage discloses a reset button that will zero the display (col. 8, lines 1-3). The amount of fluid is displayed in volume (col. 6, lines 57-60).

23. Claims 5, 8, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Ognier as applied to claims 1, 10 above, and further in view of Dunberger et al (US 5,399,160). Savage and Ognier fail to disclose that the tubing is formed from PVC. Dunberger teaches an irrigation tubing set wherein the tubing is formed from PVC. PVC is commonly used in medical tubing because it is biocompatible, flexible and sterilizable. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Savage in view of Ognier to include tubing formed from PVC as taught by Dunberger because PVC is a commonly used material in the medical arts because of its flexibility, biocompatibility and ability to be sterilized.

**24. Claims 10, 11, 14, 15, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blugerman et al (US 5,447,493) in view of Savage.**

25. Blugerman teaches a method for delivering a desired volume of sterile fluid to a targeted anatomical site during a lipoplasty procedure, the method comprising the steps of connecting one end of a sterile tubing set to the container and connecting the container to a peristaltic pump to deliver the fluid to an anatomical site in a lipoplasty procedure, monitoring the amount of fluid pumped to the site and releasing the pump activation when the desired volume of fluid is delivered (col. 3, lines 49-55).

26. Blugerman discloses that the reservoir has a capacity of 250 cc to 2000 cc, up to 3000 cc for certain applications (col. 6, lines 1-5) but fails to disclose that the peristaltic pump delivers the fluid at a rate in the range of 30 ml/min to 1000 ml/min. However, these limitations would

have been obvious to one of ordinary skill in the art. Peristaltic pumps are known to have adjustable flow rates. The device of Blugerman is used to perform the same procedure as the claimed invention and therefore would operate under the same flow conditions. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Blugerman so that the peristaltic pump operates with the claimed flow rates and volumes because peristaltic pumps are capable of operating under a wide variety of flow rates and the claimed flow rate and volumes are suitable for lipoplasty procedures.

27. Claim 10 differs from Blugerman in calling for the steps of supporting the container from strain gauge sensors that provide an electronic signal indicative of the weight of the container and processing the signal to determine and display the volume of fluid removed from the container. Blugerman teaches that the amount of fluid delivered is controlled by the surgeon. The tumescent fluid delivered is known to contain agents that are toxic in high volumes. Savage teaches a method for delivering and monitoring the delivery of a desired volume of fluid to a targeted anatomical site comprising the steps of supporting the fluid from a strain gauge sensor that provides an electronic signal indicative of the weight of the container, processing the signal from time to time to determine the volume of fluid delivered and monitoring the amount of fluid pumped to the target site and displaying the volume of fluid delivered (see above). The processor can determine the volume of fluid removed from the container regardless of the rate of removal of fluid because the strain gauge measure the weight of the fluid which is independent of the rate of flow into or out of the container. This method of monitoring the amount of fluid delivered is very accurate. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Blugerman to include the monitoring system of Savage

so that the amount of fluid delivered can be precisely monitored because the fluid contains potentially harmful drugs that can cause complications if an excessive amount is delivered.

28. Regarding claim 11, Savage teaches that the container is hanging from the strain gauge. Therefore, this feature is included in the combination described above.

29. Regarding claims 14, 17, Blugerman discloses that the tubing is PVC (col. 5, lines 52-54).

30. Regarding claims 15, 18, Savage discloses that the amount of fluid is displayed in either weight or volume (col. 4, lines 52-53). The combination described above includes this feature.

**31. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maddock et al (US 5,549,672) in view of Savage in view of Blugerman.**

32. Maddock discloses a method for delivering and monitoring the delivery of a desired amount of fluid to a breast implant or sizer comprising the steps of supporting a container of sterile fluid, connecting the end of a sterile tubing set to the container, making the other end available for delivery to the implant, and monitoring the amount of fluid delivered (col. 2, lines 50-60).

33. Maddock discloses that the volume of fluid delivered is measured using markings on the bag of sterile fluid, but fails to disclose the strain gauge and processor as claimed. Savage teaches that using the markings on the fluid bag is a known method of measuring volume, but that it is inaccurate for a variety of reasons (col. 1, lines 25-37). Savage provides an improved method of monitoring the volume delivered using a strain gauge and a processor to process the signal from the strain gauge and display the volume of fluid delivered on a display (see above for full citing of relevant Savage disclosure). It would have been obvious to one of ordinary skill in

the art at the time of invention to modify the device of Maddock to include the monitoring method of Savage because Savage teaches that using a strain gauge and processor is a more accurate way of monitoring the amount of fluid delivered than using the markings on the bag as disclosed by Maddock.

34. Claim 23 further differs from Maddock in calling for a peristaltic pump. Maddock discloses that the fluid is provided through the tubing using an inflation cuff to force the fluid out of the bag (col. 4, lines 28-31). Blugerman teaches that the use of a pressure cuff to squeeze fluid out of a bag during cosmetic procedures is known, but a peristaltic pump is preferable because it allows the user to have more control over the delivery of fluid (col. 3, lines 45-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Maddock to include a peristaltic pump as taught by Blugerman because a peristaltic pump is a known improvement over the pressure cuff system of Maddock.

35. The combination above fails to disclose the claimed volume or flow rate of the fluid. However, it would have been obvious to one of ordinary skill in the art to deliver the fluid in the claimed amount at the claimed rate because Maddock is used to fill breast implants and would therefore require an amount of fluid consistent with that procedure, and Blugerman discloses that use of a peristaltic pump which is known to have an adjustable and versatile flow rate.

36. Regarding claim 24, Blugerman teaches that the tubing set can be formed of PVC which is transparent so that the user can observe the flow of material through the tubing (col. 5, lines 53-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the tubing set of Maddock to be formed from PVC as taught by Blugerman

because sterile tubing sets are commonly formed from PVC so the user can observe the flow of fluid through the tube to ensure that the system is functioning properly.

37. Regarding claim 25, Savage teaches that the display shows the amount of fluid in either volume or weight. This feature is included in the combination described above.

**38. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Ognier as applied to claim 1 above, and further in view of Blugerman.**

39. Blugerman teaches that for certain infusion procedures an additive is added to the sterile solution to prevent bleeding and to numb the area to eliminate the need for general anesthesia thereby increasing the safety of the procedure (col. 2, lines 28-35). The additive may be lidocaine or epinephrine (col. 2, lines 28-29). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Savage in view of Ognier to include an additive as taught by Blugerman to eliminate the need for anesthesia and reduce bleeding thereby increasing the safety of the procedure.

### *Conclusion*

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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